IRBx

IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Quarterly Call: Study Managers

- Study & User Support
- Materials Development

Katelyn Benhoff

- Training & User Support

Natalie Dilts

- Lead Application Developer

Bryce Embry

- Study Support
- New Features

Carrie Smith

- Project Director

Emily Serdoz

- Onboarding
- Study & User Support

David Crenshaw

- Onboarding
- Study Support

Bridget Swindell

- System Development
- Study Support

Linda Tan

- Application Developer

Jason Tan

- Application Developer

Evan Wimberly

7.15.2022 STUDY MANAGERS QUARTERLY CALL AGENDA

- Welcome
- Announcements
- Recent System Updates
- Other feature releases for 2022

About the IREx Quarterly Calls

hear • new • features

- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!

learn • new • trends

- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?

share • your • voice

- Give your opinion
- Ask your questions
- Express your needs

Announcements

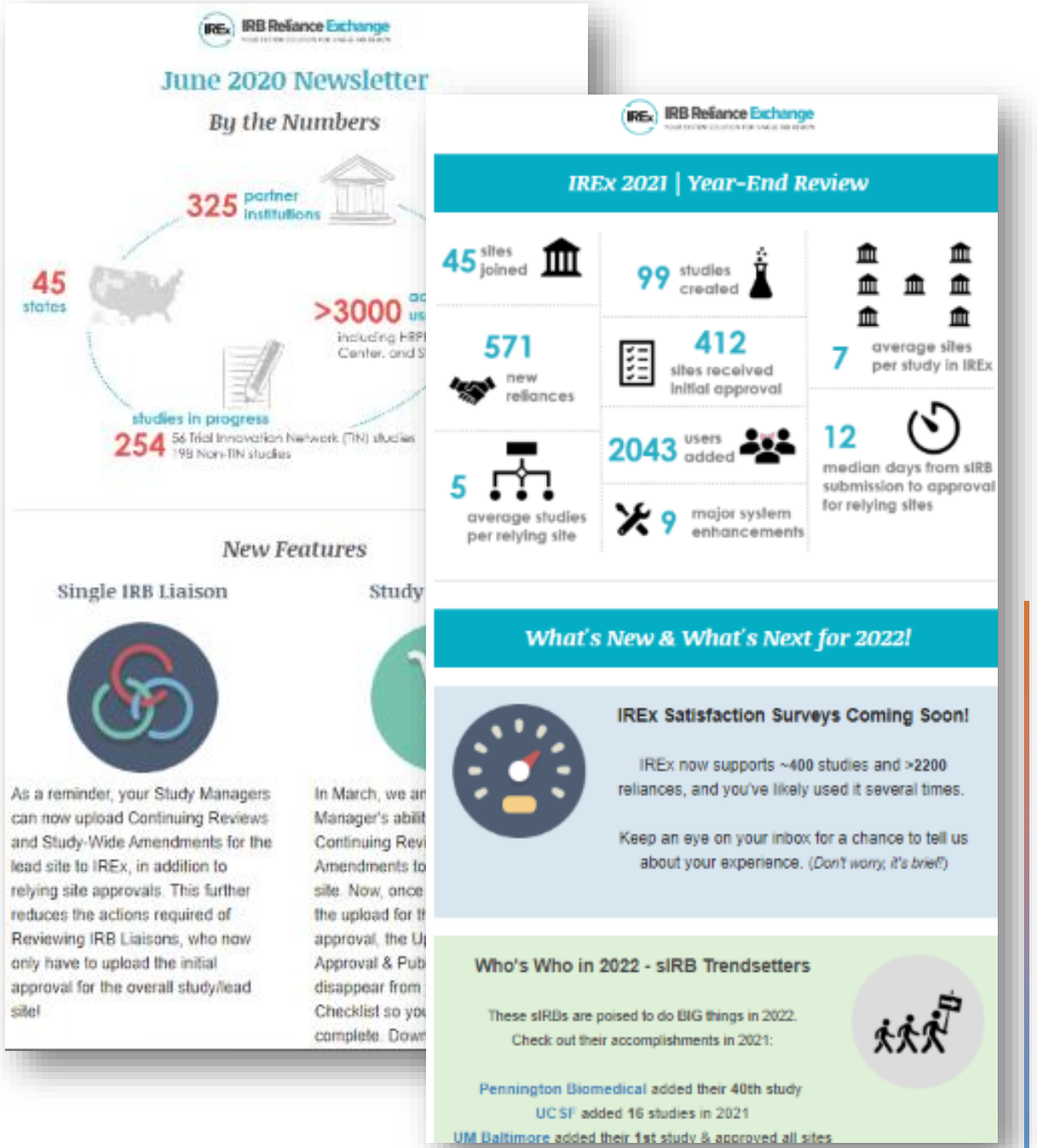
Upcoming Calls

- After today, our calls will combine HRPPs and lead study teams
- October 21st, 2022
- January 20th, 2022
- April 21st, 2023
- July 21st, 2023
- **Zoom:** https://zoom.us/meeting/register/tJwud-irrzoiHtKcmf1BEmwhqm7YvXg0rhYq

The IREx monthly newsletter is coming back!

Check out past issues:

https://www.irbexchange.org/p/newsletters/



Join us Friday, October 21st

1 PM ET/12 CT/11 MT/10 PT

when the

SMART IRB Team presents on the IREx Quarterly Call

IREx on March 2022 SMART Talk Webinar:

- Intro Slides: https://smartirb.org/assets/files/SMART_Talk_Intro_Slides_March2022_sIRBInvestigatorPerspective_FINAL-ua.pdf
- Recording: https://player.vimeo.com/video/689280786

IREx SATISFACTION SURVEYS

- **Respondents**
  - **sIRB Liaisons**, after uploading lead site approval
  - **Study managers**, after a few relying sites get approval
  - **PSite HRPPs**, after receiving approval from sIRB
- **Satisfaction with using IREx…**
  - on THIS study
  - in general
  - resources
- **Are there features we should improve/add**
- **Participating Site experience**
- ***NEW* Quarterly drawing for $50 gift card!**
  - **sIRB Liaison:** Jennifer Beck, Nationwide Children's Hospital
  - **Participating Site HRPP Liaison:** Lubabah Helwani, University of California, Los Angeles
  - **Study Manager:** Ben Bagwell, Wake Forest University Health Sciences

Operational Challenge	IREx Solution	Advantages	Utilization
Documenting reliance & flexible elements of reliance agreement	Study-specific Reliance Plan (SSRP) / SMART IRB Implementation Checklist	• Electronic documentation & automated emails • Easily customizable for individual sites • Centralized historical reference	>2300 reliances
Standardizing "local considerations" questions & processes	Capture static information via the Institutional Profile and study-specific information from the HRPP & PI in the HRP & PI Surveys	• Electronic documentation • Collaborative HRPP & PI documentation • Central repository (instead of email) • Facilitative communications	• 291 of 378 IREx studies (79%) capture local considerations • 362 (87%) completed IPs
Supporting sIRB coordination	Empower and equip lead study teams to support sites thru sIRB review and communicate sIRB approvals with sites	• Minimize work for the sIRB • Automate site tracking / progress • Automate sIRB approval communications • IREx Admin Support & Training for lead study teams	• >400 lead study team members • Relying site time to approval is improving each year
Capturing sIRB metrics systematically	Capture all timepoints in the sIRB review & approval process	• Identify averages / standards • Identify common bottlenecks • Report to policy makers	• Steadily increasing use by new sIRBs each year • Data highlight improvements & ongoing challenges

IREx PUBLICATION

Takeaway: HRPPs and study teams need tools to operationalize the national sIRB mandate – IREx can help!

Serdoz, E., Edwards, T., Pulley, J., Beadles, J., Ozier, J., Harris, P., . . . Rice, T. (2022). The IRB Reliance Exchange (IREx): A national web-based platform for operationalizing single IRB review. *Journal of Clinical and Translational Science, 6*(1), E39. doi:10.1017/cts.2022.376

IREx Utilization – Quarterly Update

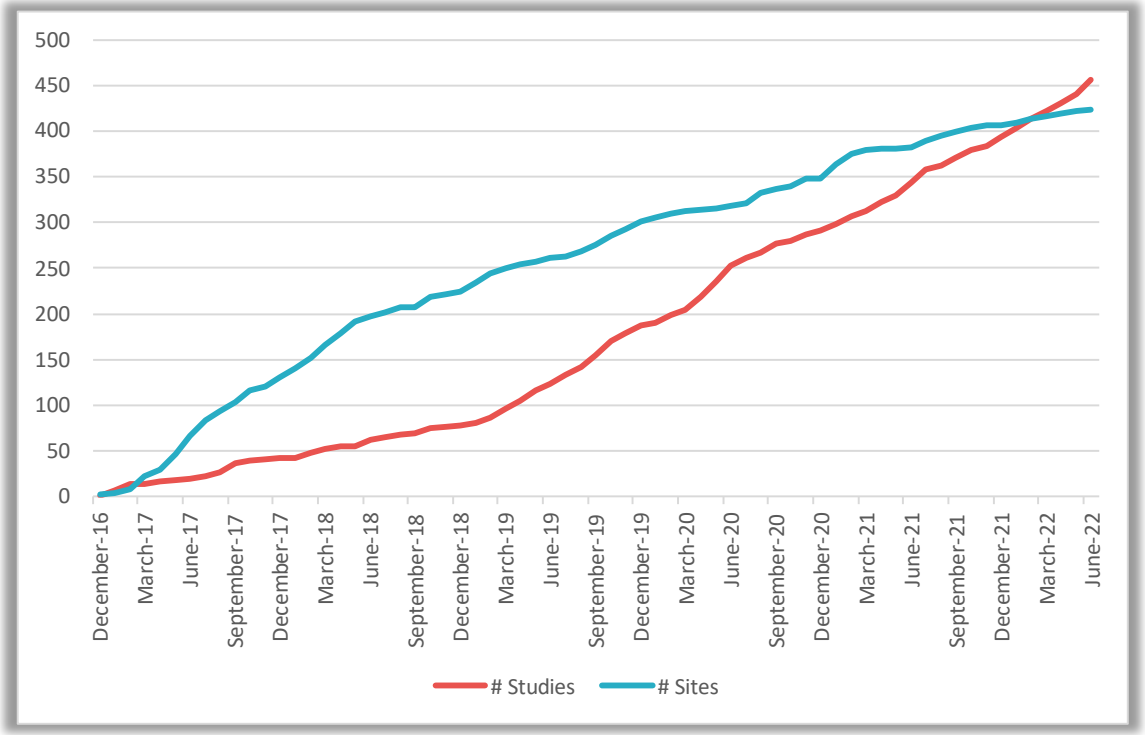
88% of IREx Institutional Profiles are complete (n=377!)

81% of IREx sites have indicated reliance on 1+ studies

- 37 sIRBs using IREx (view here)
- 2602 instances of reliance

89% of ceded sites have sIRB approval in IREx

- 11 days from sIRB submission to approval for PSites
- 17 days for local HRPP review
- 51 days from lead site approval to local HRPP submission



Recent System Updates

Since January 2022

Complete IREx API for sIRBs

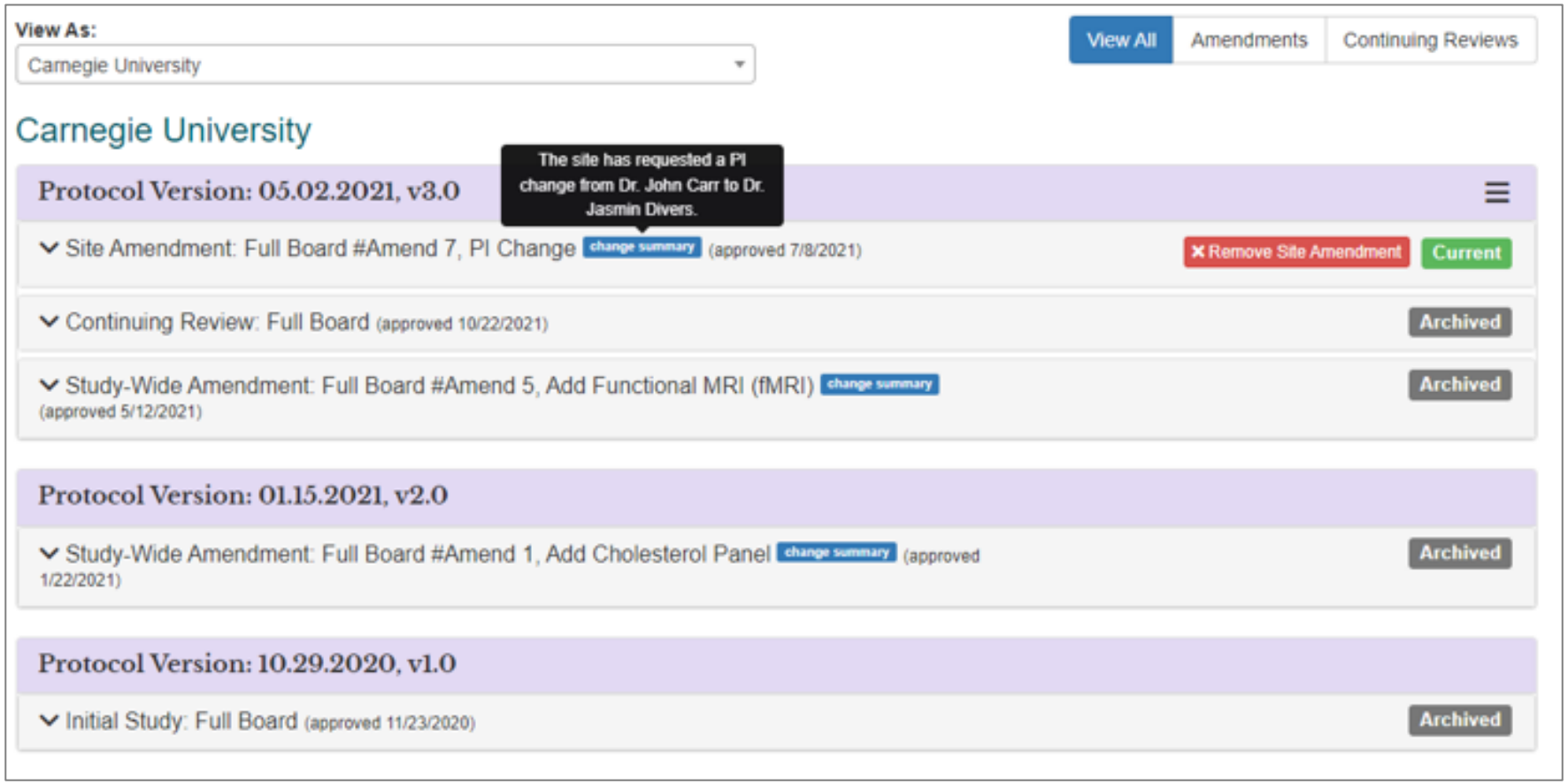
- POST: Study shell to IREx (title, sIRB, sponsor, etc)
- POST: Study initial approval for the lead site (risk categories, review dates, documents, etc.)
- GET: Relying site reliance information and local considerations
- POST: Relying site initial approval (review dates, documents, etc)
- POST: Additional study and site approvals (continuing review, amendments)
- POST: Site and study closures

GOALS

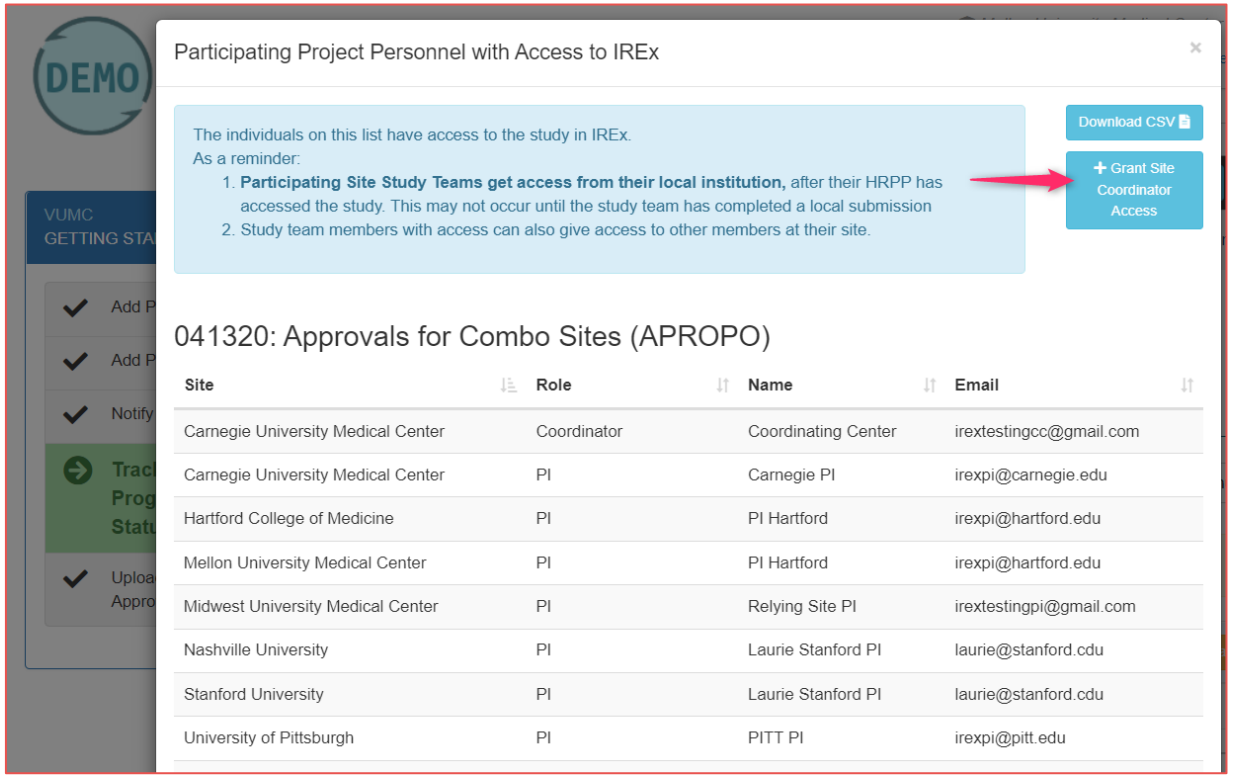
1. Minimize sIRB setup in IREx
2. Streamline ingesting of PSite local reviews
3. Streamline posting of approvals for the life of the study

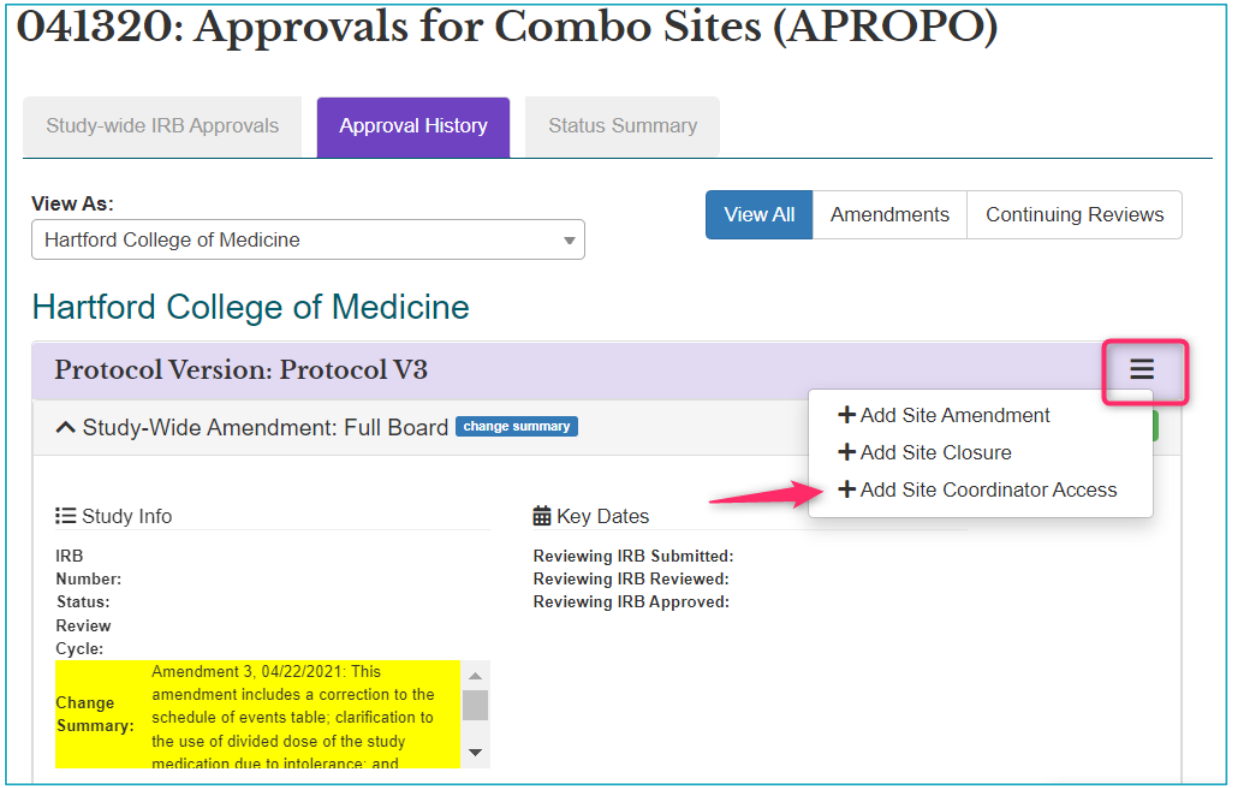
- Bi-directional API between sIRB's electronic system and IREx
- System agnostic – can connect with any e-IRB system
- General information: https://www.irbexchange.org/p/irex-integration-api/
- Technical information *(IREx login required)*: https://www.irbexchange.org/s/doc/api

Relying site approval documents are all listed on a single tab

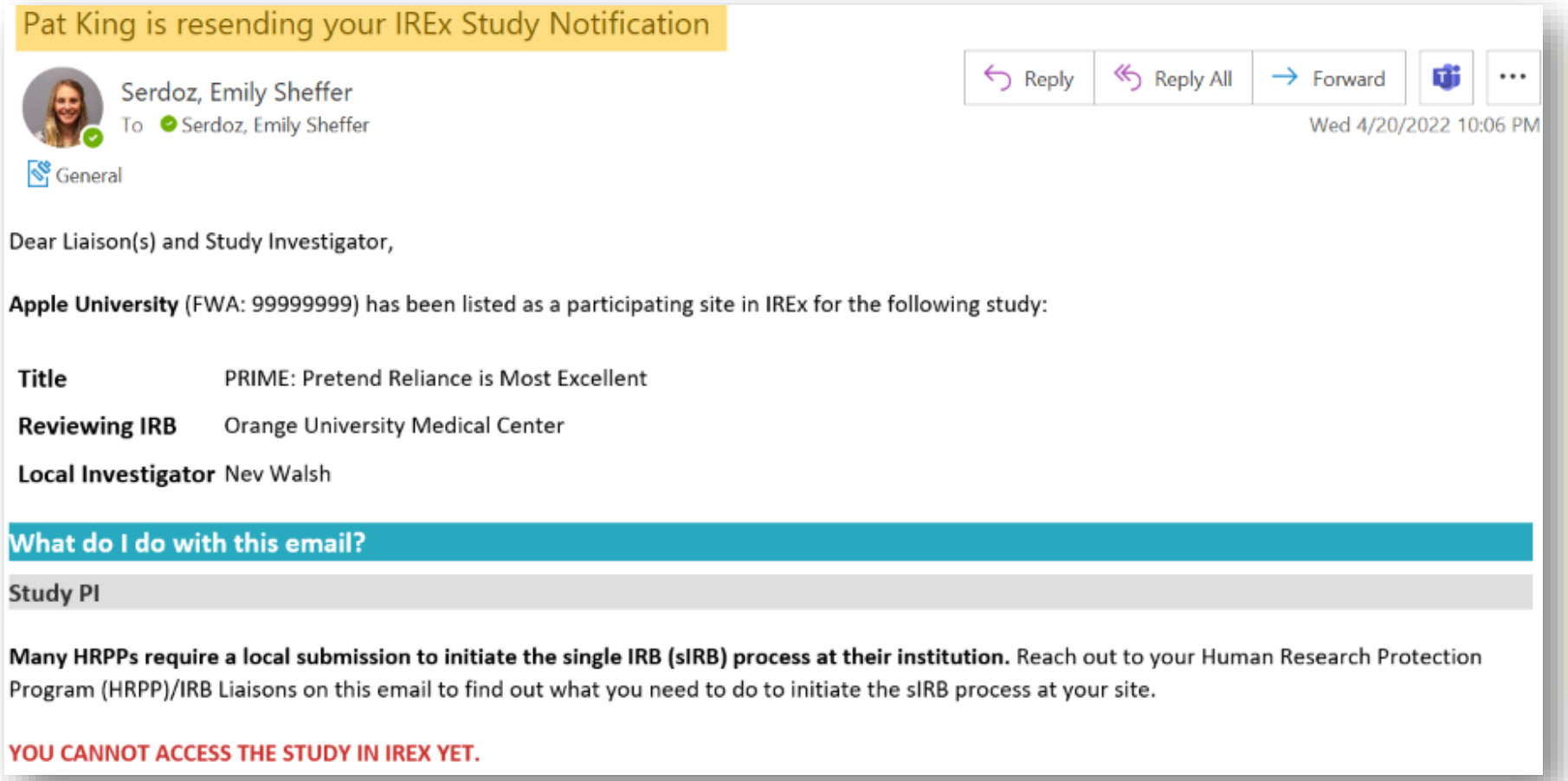


Study Managers can add access for new site coordinators and site PIs





Study Managers can re-send the 'invitation'



Pat King is resending your IREx Study Notification

Serdoz, Emily Sheffer
To Serdoz, Emily Sheffer

Reply | Reply All | Forward | ...

Wed 4/20/2022 10:06 PM

General

Dear Liaison(s) and Study Investigator,

Apple University (FWA: 99999999) has been listed as a participating site in IREx for the following study:

Title	PRIME: Pretend Reliance is Most Excellent
Reviewing IRB	Orange University Medical Center
Local Investigator	Nev Walsh

What do I do with this email?

Study PI

Many HRPPs require a local submission to initiate the single IRB (sIRB) process at their institution. Reach out to your Human Research Protection Program (HRPP)/IRB Liaisons on this email to find out what you need to do to initiate the sIRB process at your site.

YOU CANNOT ACCESS THE STUDY IN IREX YET.

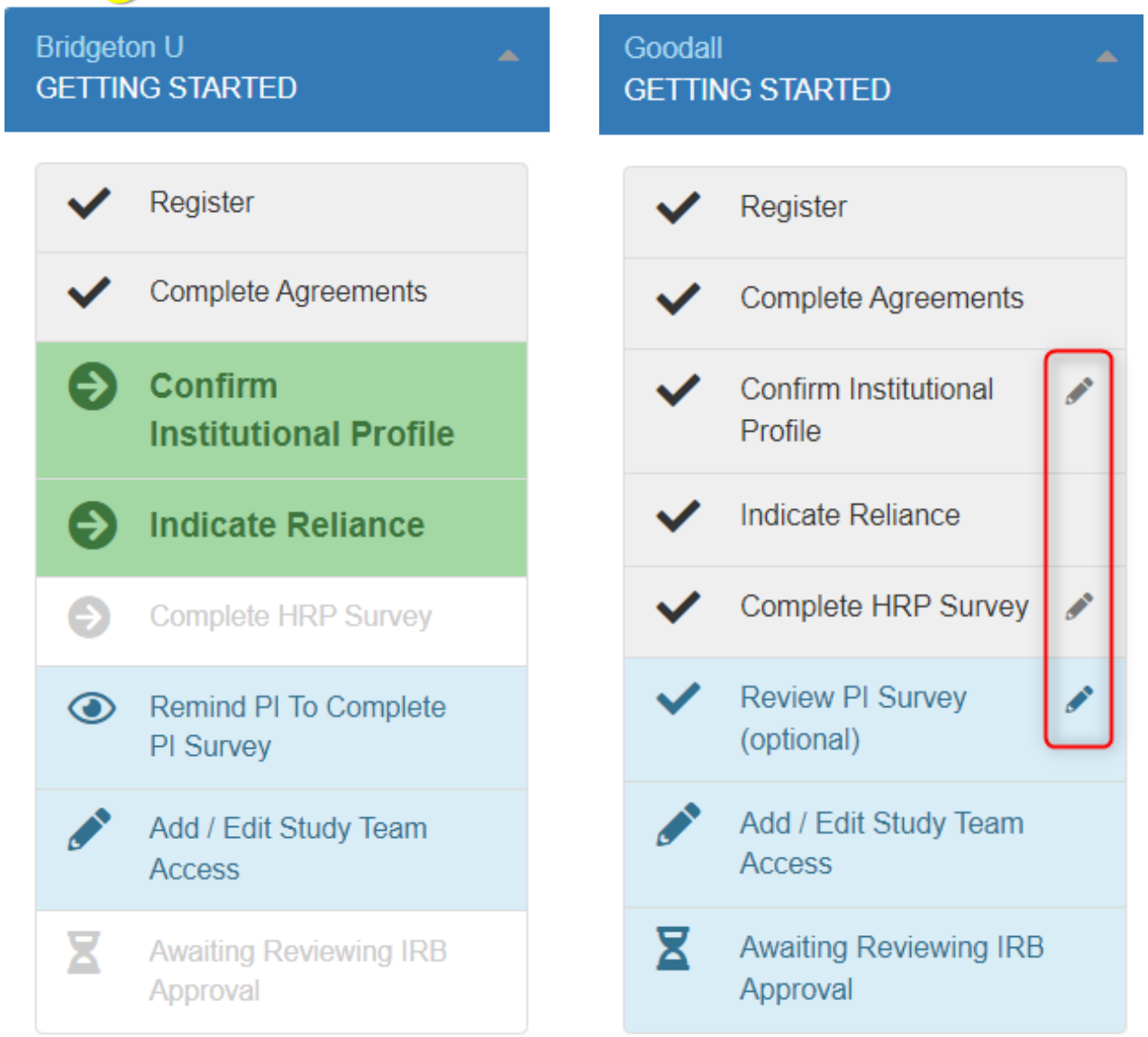
No action required of HRPP at this point.

This goal of this email is to connect the HRPP and their local study team around next steps for initiating reliance at their site.

Upcoming Feature Enhancements

Coming in the next few weeks…

Coming soon!

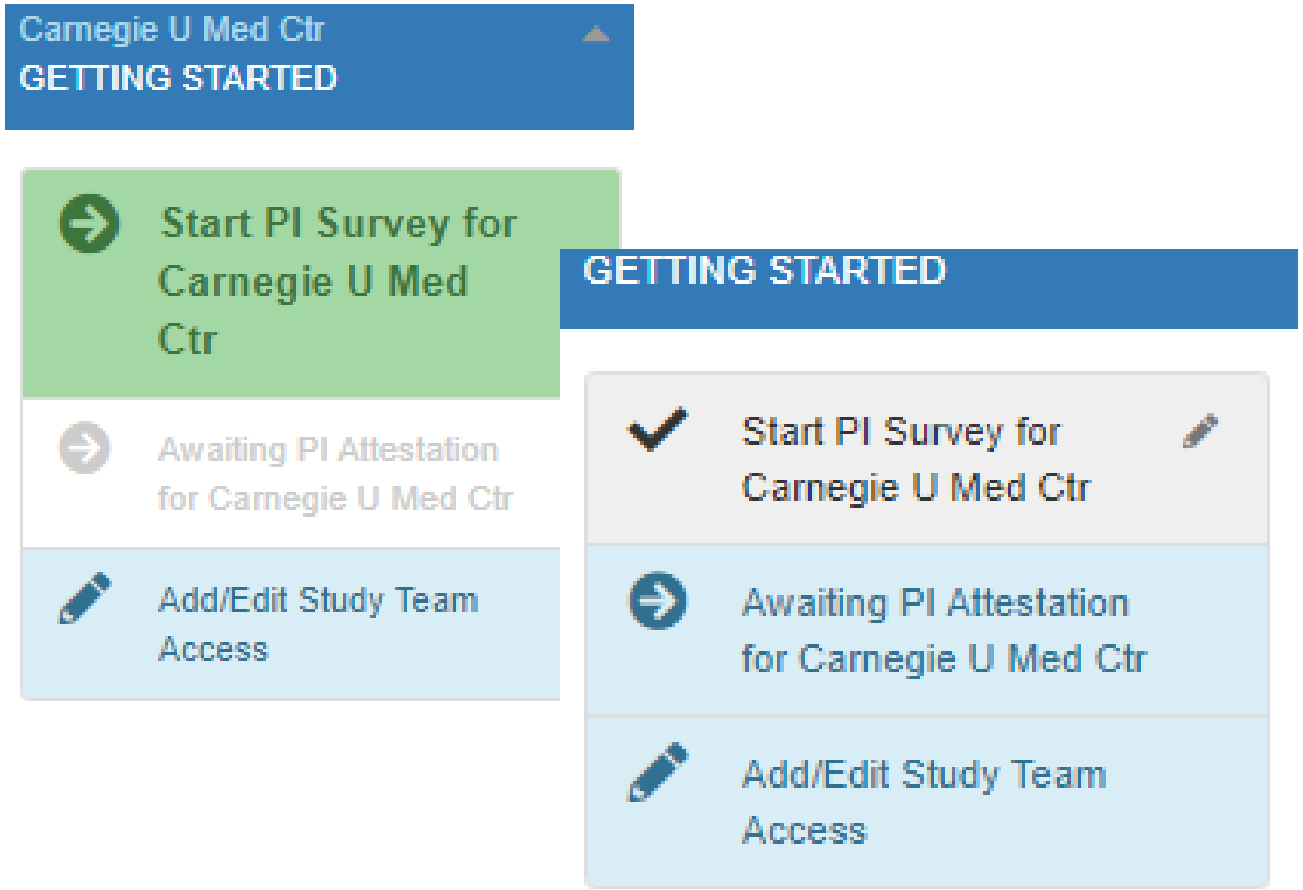


Simplifying Local Considerations Documentation – RELYING HRPPs

Relying HRPPs will no longer have to…

1. **Upload their site's ICF to the HRP Survey (**it is now upload to the PI Survey)
2. Validate the PI Survey (though you can still view & edit it)
3. Add/edit local study team (optional step)

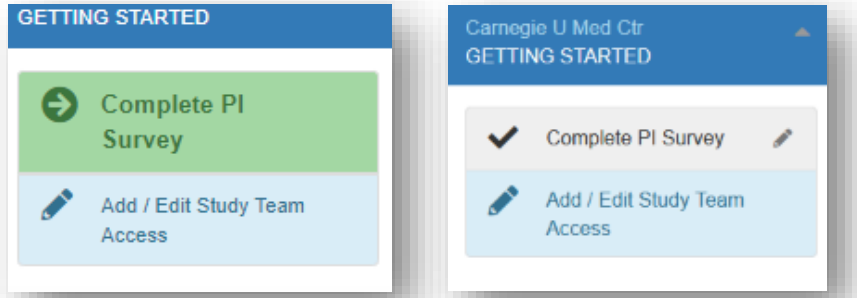
Coming soon!

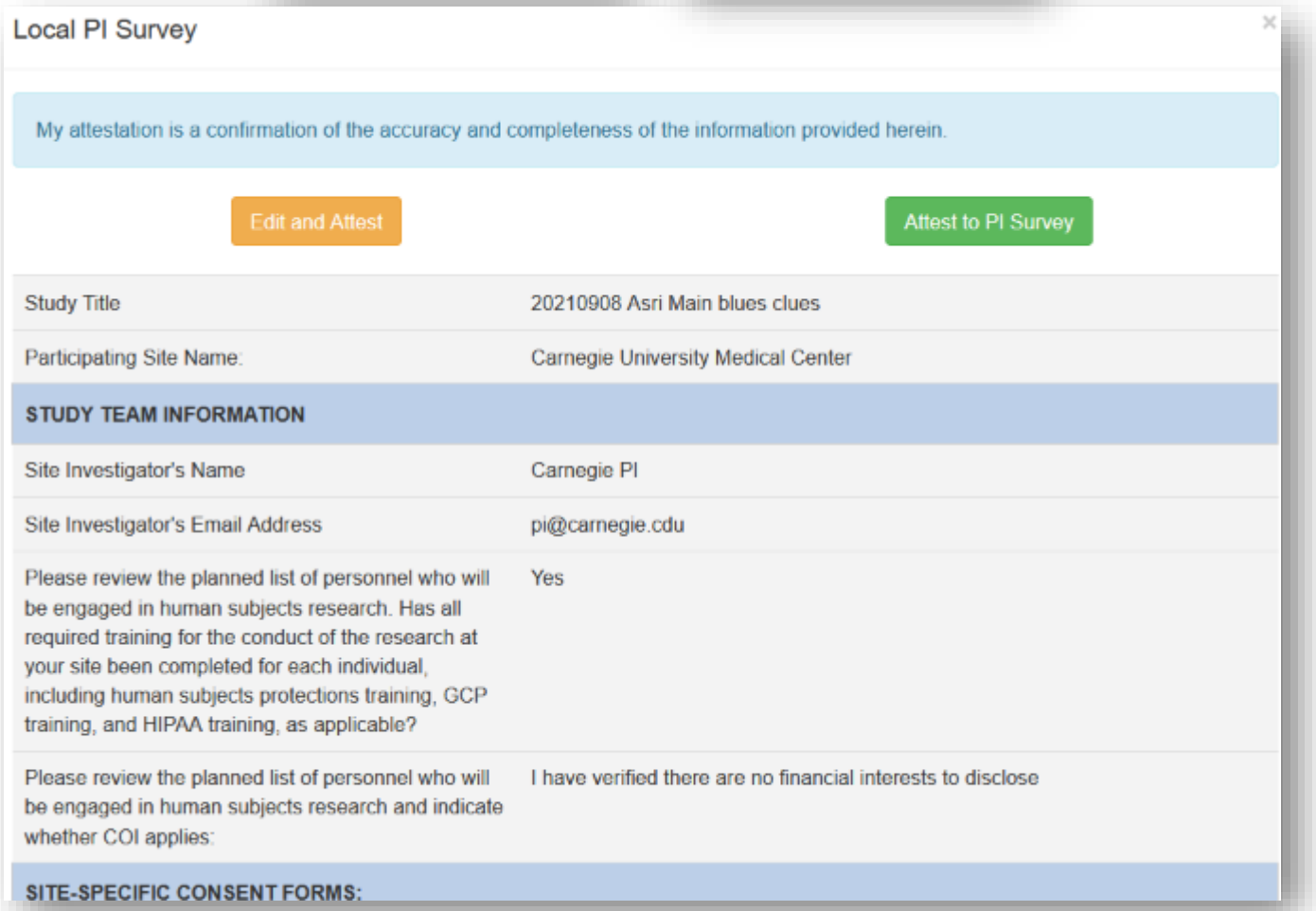


Simplifying Local Considerations Documentation – COORDINATORS

- **Coordinators can complete the PI Survey**
- PI attestation required
- Edits can be made after PI attestation (requires new attestation)
- **Local consent form is attached to PI Survey instead of HRP Survey**

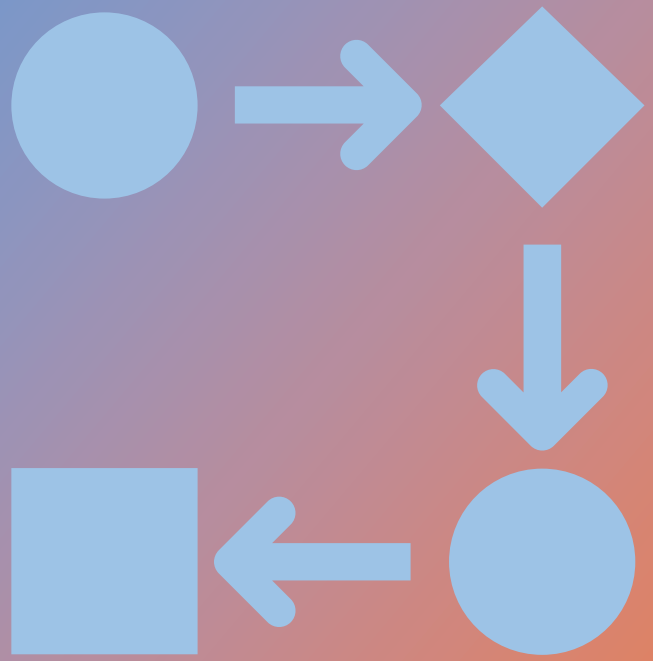
Coming soon!





Simplifying Local Considerations Documentation – INVESTIGATORS

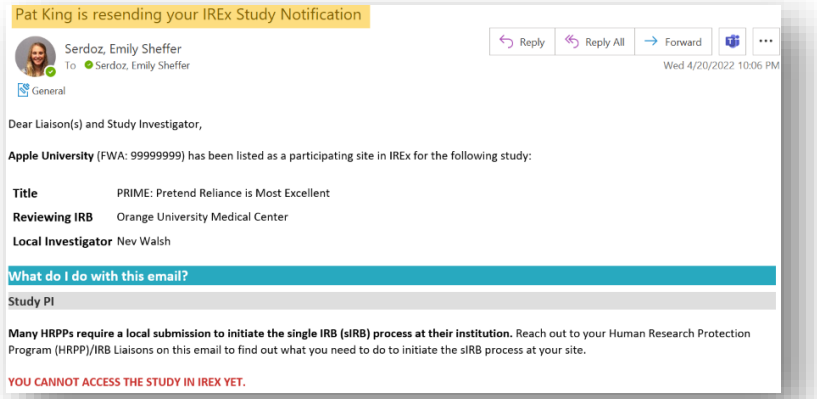
- PI attestation required
- Edits can be made after PI attestation (requires new attestation)
- **Local consent form is attached to PI Survey instead of HRP Survey**



What does this mean for the HRPP workflow when relying on an sIRB?

New Workflow – Only ONE IREx Log In!

1 Notified of study in IREx



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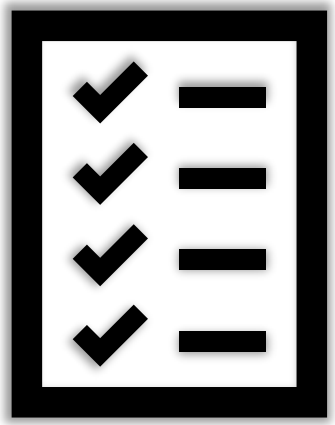
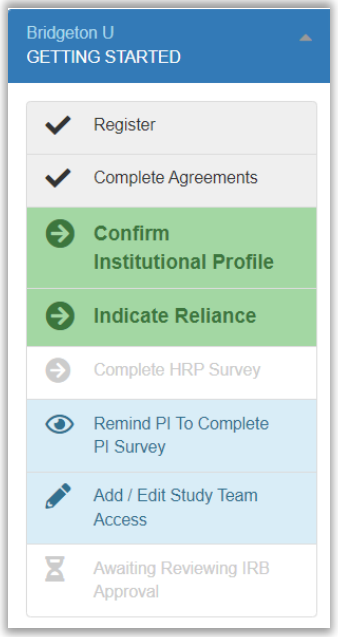
Share local reliance process with study team

2 Complete local reviews



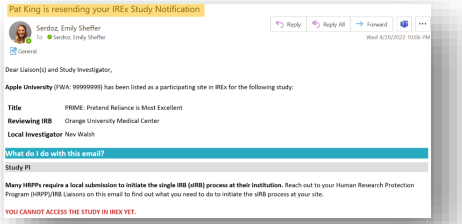
3 Login to IREx



- Study team access is granted when HRPP registers
- HRPP notified when PI Survey is completed, if you want to see it

Workflow for HRPPs that prefer to see the PI Survey before it goes to the sIRB

1 Notified of study in IREx

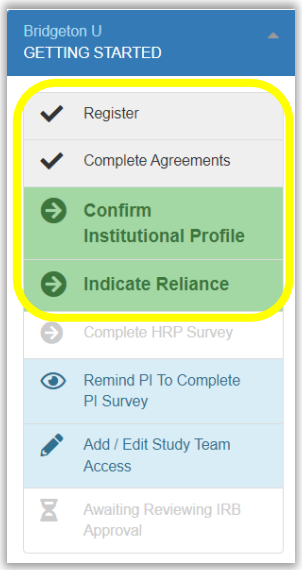


Share local reliance process with study team

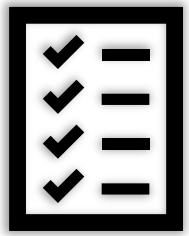
2 Login to IREx

OPTIONS:

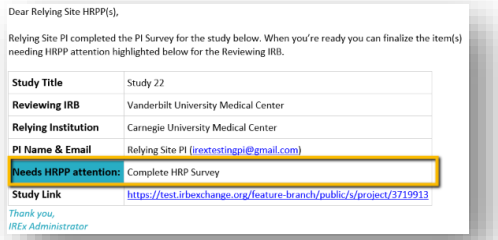
1. Log out after registering
2. Complete steps other than HRP Survey



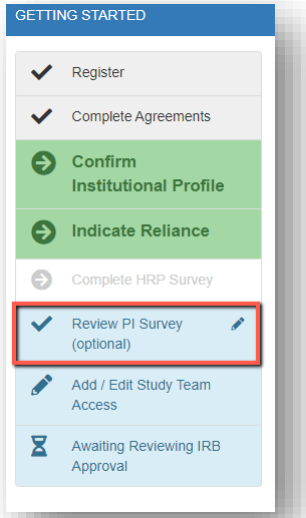
3 Complete local reviews



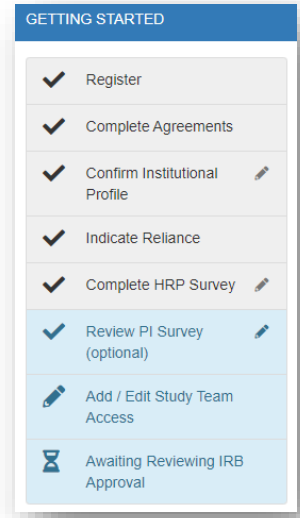
4 Notified PI Survey completed

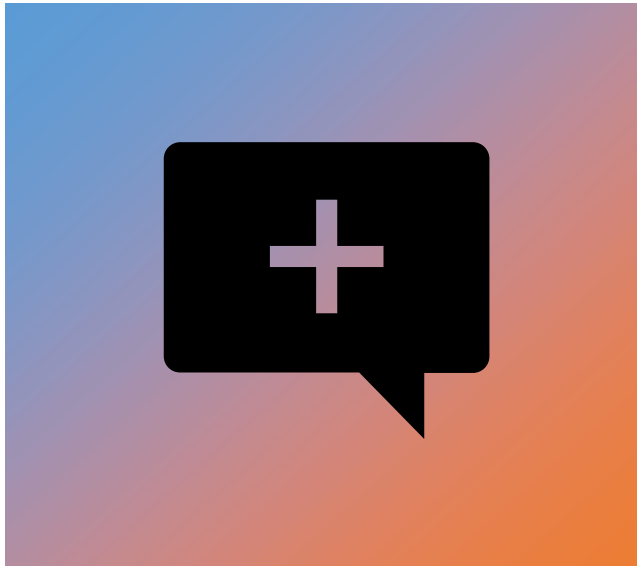


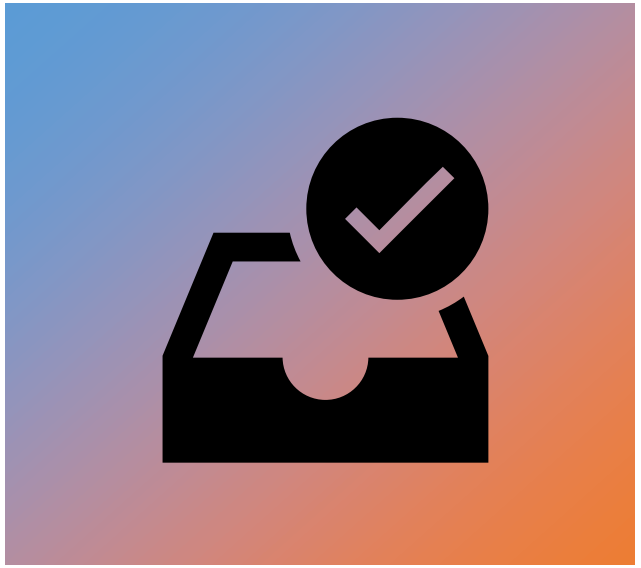
5 View/edit PI Survey



6 Complete all steps







Other Enhancements in 2022

Streamline approval uploads by…
- *Allowing study managers to post initial approval for the lead site*

- *Automating approvals of relying sites on study-wide amendments when possible*

Grant PSite study team access to lead site's approvals prior to site registration to…

-Reduce SM burden of emailing lead site approval to sites
-Improve workflow for study teams
-Minimize need for Relying HRPP to log into IREx multiple times

Capture other sIRB communications (e.g., reporting acknowledgments) to…

- Centralize ALL sIRB communications (not just approvals)

Next Call: October 21, 2022

NEW TIME: CALL WILL BE AT 1 PM ET/12 CT/11 MT/10 PT

Zoom: https://zoom.us/meeting/register/tJwud-irrzoiHtKcmf1BEmwhqm7YvXg0rhYq